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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,591	06/02/2000	ANDREW S. LITTLE	348022000420	3648

7590 03/25/2002
Cell Genesys, Inc.
342 Lakeside Drive
Foster City, CA 94404

EXAMINER

GUZO, DAVID

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 03/25/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/509,591

Applicant(s)

LITTLE ET AL.

Examiner

David Guzo

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 71-94 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 71-75, 79, 82-87, 91 and 94 is/are rejected.
- 7) ☒ Claim(s) 76-78, 80, 81, 88-90, 92, 93 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/2/00 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.

- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 71-75, 79, 83-87, 91 are rejected under 35 U.S.C. 102(e) as being anticipated by Hallenbeck et al. (Cited by applicants).

Both applicants and Hallenbeck et al. (U.S. Patent 5,998,205, issued 12/7/99, effective filing date 11/28/94, see whole document, particularly Claims 1, 3, 14, Columns 4, 8, 10 and 13-15 and Example 1) recite a method for conferring selective cytotoxicity on a target cell *in vitro* or *in vivo* comprising administering an adenoviral vector comprising an adenovirus gene essential for replication (which can be early genes such as E1a, E1b, E4, etc.) under transcriptional control of an AFP-TRE which comprises a promoter and enhancer. Both applicants and Hallenbeck et al. also recite a method for suppressing tumor growth in an individual having an AFP-expressing

Art Unit: 1636

tumor (See Example 1) comprising contacting the tumor cells with the aforementioned adenoviral vector. Therefore, Hallenbeck et al. teaches the claimed invention.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 82 and 94 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 35, 37 of U.S. Patent No. 6,254,862 (hereafter the '862 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite the same methodologies for conferring selective cytotoxicity on target cells and the same methodologies for suppressing tumor growth in patients. Both sets of claims recite use of the replication competent adenoviral vectors wherein two early genes are under control of separate AFP-TREs. The instant claims are broader than the issued claims in that the two adenoviral genes under control of the AFP-TREs can be any adenoviral early genes, not just the early genes E1a and E1b genes recited in the issued claims. It would have been obvious for the ordinary skilled artisan to use the

Art Unit: 1636

patented methods for killing target cells or suppressing tumor growth in order to generate the instant invention because the claims in the patent recite the same methodologies for killing cells or suppressing tumor growth and use replication competent adenoviral vectors wherein two early genes are under transcriptional control of separate AFP-TREs. The ordinary skilled artisan would have been motivated to do this because the patented claims recite the success in conferring selective cytotoxicity on target cells and suppressing tumor growth in patients comprising administering replication competent adenoviral vectors wherein two essential early genes are under control of separate AFP-TREs. Given the teachings of the claims in the '862 patent and the level of skill of the ordinary skilled artisan at the time the invention was made, it must be considered that the ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention. Also, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the '862 patent, then two different assignees would hold a patent to the claimed methods of the '862 patent and thus improperly there would be possible harassment by multiple assignees.

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Art Unit: 1636

The filing date for the 09/509,591 application is erroneously listed as 9/3/99 rather than the correct date of June 2, 2000.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

The Continuing Data on page 1 of the specification is unclear. The relationship between the instant application and the 09/033,428 application is unclear. Also, the filing date of the 60/039,597 application is incorrect. The correct filing date is March 3, 1997.

There are blanks (where U.S. Serial Numbers should be) on page 33 of the specification. Applicants are required to supply the missing Serial Numbers.

The Sequence Listing filed 11/7/00 is acceptable and has been entered.

No Claims are allowed.

Claims 76-78, 80-81, 88-90, 92 and 93 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Application/Control Number: 09/509,591

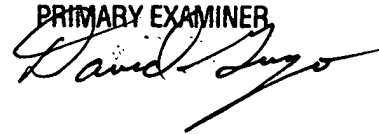
Page 6

Art Unit: 1636

Any inquiry of a general nature or relating to the status of this application or proceeding or relating to attachments to this Office Action should be directed to Patent Analyst Zeta Adams whose telephone number is (703) 305-3291.

David Guzo
March 20, 2002

DAVID GUZO
PRIMARY EXAMINER

A handwritten signature in cursive script, appearing to read "David Guzo", written over the printed name and title.